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JUN 28 2011

510(k) Summary

Vasomedical-Biox 12 - Channel Ambulatory ECG Holter Recorder, Model 1304 Vasomedical-Biox 3 - Channel Miniature Ambulatory ECG Holter Recorder, Model 1303

1. **Date Prepared:** April 25, 2011

2. **Submitter's Name: and Address** Vasomedical, Inc.
180 Linden Ave.
Westbury, NY 11590

3. **Contact Person:** Richard Gordon
Manager, Regulatory and Quality Affairs
Vasomedical, Inc.
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4. **Device Names:**
a) 12 - Channel Ambulatory ECG Holter Recorder, Model 1304
b) 3 - Channel Miniature Ambulatory ECG Holter Recorder, Model 1303

Proprietary Names:
a) Vasomedical-Biox 12 - Channel Ambulatory ECG Holter Recorder, Model 1304
b) Vasomedical-Biox 3 - Channel Miniature Ambulatory ECG Holter Recorder, Model 1303

Common Name:
a) 12 - Channel Ambulatory ECG Holter Recorder, Model 1304
b) 3 - Channel Miniature Ambulatory, ECG Holter Recorder, Model 1303

Classification Name: 870.2800 Magnetic Tape Recorder, Medical

5. **Predicate Device:** Vasomedical - Biox, 3 - Channel Ambulatory ECG Holter Recorder, Model 1305 was granted **FDA 510(k) clearance on April 1, 2009 (k083820).**

6. **Device Description:** Vasomedical-Biox 12 - Channel Ambulatory ECG Holter Recorder and Vasomedical-Biox 3 - Channel Miniature Ambulatory ECG Holter Recorders are intended to be used as a Holter Ambulatory Electrocardiograph device for the purpose of screening ECG rhythms for periods ***up to*** 72 hours. Cardiac rhythm is acquired by 12 Channel or 3 Channel ECG signals.

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The Recorders are intended for adults and children over the age of six years old.

The Models 1304 and 1303 are modified versions of Model 1305 which **FDA granted clearance on April 1, 2009 (k083820).** Model 1304 increases the number of channels and ECG signals to 12 from 3 as in the Predicate device Model 1305.

Model 1303 is a miniaturized version of Model 1305

The Recorders are portable, microprocessor based devices that are worn by a patient with the use of a supplied Carrying Case and Strap.

Models 1304 and 1303 specifications are listed in **Table 1** below:

	Model 1304	Model 1303
Lead	12	3
Electrode	10	5
Lead wire type	10F/10G	7E/5E
Display	LED	LCD
Batteries	1 x "AA" Alkaline	1 x "AAA" Alkaline
Carrying Case/ Strap	Supplied	Supplied
Card Reader	Supplied	Supplied
Dimensions	3.3 x 2.3 x 0.88"	2.6 x 2.1 x 0.7"
Weight	2.45 oz.	1.76 oz.
Storage	SD Memory Card	SD Memory Card
Memory Capacity	1 GB or more	1 GB or more
Sample Rate	256 Hz/Channel 10,000 Hz Pacemaker Detection	256 Hz/Channel 1,000Hz for SAECG option
Resolution	10 Bit	10 Bit; 12 Bit for SAECG option
Infrared Adaptor	Supplied	Supplied

Table 1: Model 1304 and 1303 Specifications

7. Intended Use:

Vasomedical-Biox 12 - Channel Ambulatory ECG Holter Recorder, **Model 1304**, is a Non-Invasive device intended to acquire ambulatory 12 - Channel ECG signals from the upper body surfaces. Cardiac rhythm is acquired via ECG signals.

Vasomedical-Biox 3 - Channel Miniature Ambulatory ECG Holter Recorder, **Model 1303**, is also a Non-Invasive device but intended to acquire ambulatory 3 - Channel ECG signals from the upper body surfaces. Cardiac rhythm is also acquired via ECG signals.

The Holter Recorders are intended for adults and children who are over the age of six years.

The Models 1304 and 1303 work with the CB Series ECG Analysis Software which has been previously cleared under **(k)083820**

The system is only for measurement, recording and display. It makes no diagnosis.

Refer to Attachment I and II, Vasomedical-Biox Model 1305/1304 AECG Instruction Manual for Users and Model 1303 AECG Instruction Manual for Users, Sections 2.2, Indications for Use, 2.2.1 Intended Use and 2.2.2 for Contraindications.

8. Comparison of Technological Characteristics:

Technological and functional characteristics of the devices listed in this Special 510(k) Notification for Modification are essentially the same as those of the Predicate device. The devices listed in this 510(k) Premarket Notification is therefore substantially equivalent to the predicate device.

"The Intended Use of the modified devices as described in its labeling, has not changed as a result of the modifications".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Vasomedical, Inc.
c/o Mr. Richard E. Gordon
Manager, Regulatory and Quality Affairs
180 Linden Avenue
Westbury, NY 11590

JUN 28 2011

Re: K111180
Trade/Device Name: Vasomedical-Biox 12-Channel Ambulatory ECG Holter Recorder (Model 1304) and Vasomedical-Biox 3-Channel Miniature Ambulatory ECG Holter Recorder (Model 1303)
Regulatory Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: II (two)
Product Code: DSH
Dated: June 2, 2011
Received: June 3, 2011

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: k

Device Names:

a) Vasomedical-Biox 12 - Channel Ambulatory ECG Holter Recorder, Model 1304

b) Vasomedical-Biox 3 - Channel Miniature Ambulatory ECG Holter Recorder, Model 1303

Indications for Use:

Vasomedical-Biox 12 - Channel Ambulatory ECG Holter Recorder, **Model 1304**, is a Non-Invasive device intended to acquire ambulatory 12 - Channel ECG signals from the upper body surfaces. Cardiac Rhythm is acquired via ECG signals.

Vasomedical-Biox 3 - Channel Miniature Ambulatory ECG Holter Recorder, **Model 1303**, is also a Non-Invasive device intended to acquire ambulatory 3 - Channel ECG signals from the upper body surfaces. Cardiac rhythm is also acquired via ECG signals.

The Holter Recorders are intended for adults and children who are over the age of six years.

The Models 1304 and 1303 work with the CB Series ECG Analysis Software which has been previously cleared under **(k083820)**

"The Intended Use of the modified devices as described in its labeling, has not changed as a result of the modifications"..

The system is only for measurement, recording and display. It makes no diagnosis.

Prescription Use: YES (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use: NO** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111180